IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	John Eric Tkaczyk et al.	Group Art Unit:	3626
Serial No.:	10/065,159	Examiner:	Nguyen, Tran N.
Filed:	September 23, 2002	Confirmation:	4870
For:	METHODS AND SYSTEMS FOR MANAGING CLINICAL RESEARCH INFORMATION	Atty. Docket:	RD28334-1/YOD/LIU GERD:0205

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December 22, 2008	/Patrick S. Yoder/
Date	Patrick S. Yoder

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

Appellants submit this Reply Brief pursuant to 37 C.F.R. § 41.41 and in response to the Examiner's Answer mailed on October 20, 2008. Specifically, the present Reply Brief aims to highlight the underlying deficiencies of the contentions made by the Examiner in the Examiner's Answer with respect to Brown, U.S. Patent No. 6,196,970 (hereinafter "Brown"). In the interest of brevity, Appellants have addressed below only those issues or arguments raised in the Answer which are particularly noteworthy. Accordingly, in view of Appellants' attempt to avoid repetition in this Reply, Appellants respectfully request that the Board consider the following remarks in addition to the complete arguments set forth in the Appeal Brief filed on July 28, 2008.

As an initial matter, Appellants note that a key underlying issue with regard to the Examiner's Section 102 rejection of claims 1-9, 13-25, and 29-38 is whether or not Brown discloses the selection of a template from a plurality of templates stored in a centralized database as generally recited by each of independent claims 1, 14, 17, 30, and 33. During the course of prosecution, the Examiner failed to provide a logical basis or sufficient reasoning as to why an

FDA drug testing "protocol," as disclosed in Brown, is believed to correspond to the recited "template." Instead, the Examiner's rejections appear to be based upon either a misinterpretation of Brown or an inference of facts simply not supported by the cited reference. Appellants, in the remarks below, have attempted to briefly reiterate the Examiner's points of error, as well as respond to the additional points advanced by the Examiner in the Answer.

One skilled in the art <u>would not</u> read a "protocol" as being analogous to a "template."

In the Answer, the Examiner remarked that Brown teaches that a protocol may be implemented using software and, based on this observation, made the illogical leap that software deployed on a computing device somehow constitutes a "template." *See* Examiner's Answer, p. 36. In support of this assertion, the Examiner cited a dictionary definition stating that a "template" is considered to be a "gauge or pattern ... used in making or copying something accurately." *See id.* (the Examiner citing *Webster's II Dictionary, Second Edition*). Even assuming that the dictionary definition proffered by the Examiner could be applied in the context of Appellants' claims, there is simply no reasonable basis as to how the Examiner has arrived at the conclusion that a template is analogous to a drug-testing protocol. To the contrary, Appellants reiterate that the terms "template" and "protocol" are simply *not* comparable. As noted in the Appeal Brief, a "protocol" when used in a medical context, generally refers to "a plan for carrying out a scientific study or a patient's treatment regimen." Appeal Brief, Exhibit A. Indeed, this definition appears to be consistent with the description of an FDA drug testing protocol, as discussed generally throughout Brown.

Further, Appellants reiterate that the manner in which the Examiner asserted a dictionary definition of "template" as being a *superior* reference to the description set forth in Appellants' specification is in direct contrast with the current case law. As noted in the Appeal Brief, the Federal Circuit has ruled that the specification is "single best guide" in claim construction analysis. *See Phillips v. AWH Corp.*, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005) (*en banc*). Specifically, the court stated that "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors *actually invented and intended to envelop with the claim*." *Id.* at 1328-29 (Emphasis added.) The court further noted that a correct

interpretation of a claim term is one that "stays true to the claim language *and most naturally aligns with the patent's description of the invention*." *Id.* (Emphasis added.) Appellants submit that the Examiner's reliance on a dictionary reference and flat refusal to consider the specification of the present application in interpreting the term "user-selected template" is in direct contrast with legal tenets summarized above.

With the above points in mind, Appellants respectfully direct the Board's attention to the discussion on pages 17-25 of the Appeal Brief, which notes that the specification clearly sets forth that the recited "template" is utilized in providing a *standardized* format for organizing/storing clinical study (CS) data. *See* Application, ¶ 4. Generally, this is accomplished by providing a uniform and standardized set of data fields within each template, wherein the data fields may correspond to specific data requested from a patient for a particular clinical study. *See, e.g.,* ¶ 15; Fig. 3 (data fields corresponding to a patient name, sex, medical history, weight, height, age, etc). Thus, it is respectfully submitted that one skilled in the art, when interpreting "template" in view of the specification in a manner that *most naturally aligns with the patent's description*, would clearly understand a "template" to be some type of standardized form (e.g., having a plurality of data fields) for receiving the data in a manner as to provide a standardized format, thus guaranteeing that data collected for *all* patients corresponding to a particular clinical study is uniform and standardized.

Additionally, even assuming a protocol could be considered a template, there does not appear to be anything standardized about the protocols disclosed by Brown. The method set forth in Brown is directed towards *continuously modifying* a testing protocol based upon the analysis of clinical data. *See* Brown, col. 2, ll. 58-67 (noting that the inability to modify a protocol is a problem in the prior art); col. 3, ll. 41-63; col. 7, ll. 1-6. That is, Brown intends for the protocol to *change* throughout the course of the study in accordance with patient feedback. Thus, as best understood, the drug testing protocol taught by Brown would not provide a uniform and standardized format for data collection, but would instead continuously change formats based upon updates to the protocol made using analysis of patient reactions to a tested drug, for instance.

Even assuming that a template is analogous to a protocol, Brown fails to teach or suggest a "template" is selected from a plurality of templates stored in a centralized database.

In the Answer, the Examiner responded to Appellants' arguments on pages 25-30 with regard to the above feature, by alleging that the selection of a template from a "plurality of templates stored in a centralized database" is not positively recited in the claim. *See* Examiner's Answer, p. 44. Appellants are unsure as to what basis the Examiner has reached this conclusion, as this feature is *clearly* recited by *each* of independent claims 1, 14, 17, 30, and 33. Accordingly, it is respectfully submitted that no support exists with regard to the Examiner's assertion that these features are not *positively recited* in the claims.

Moreover, to the extent that these features are recited in Appellants' claims, the only reasoning offered by the Examiner as to how Brown teaches a "plurality of templates" is that the modification or changing of a drug testing protocol during the course of a drug trial creates "older versions" of the drug testing protocol which reside in a server alongside the most current version. As discussed in detail on pages 25-30 of the Appeal Brief, the Examiner's reliance on this statement is unreasonable. The Examiner's assumption is based on the failure of Brown to explicitly teach that *old versions* of a protocol are expunged after an update or modification. At best, this statement appears to be an inference of facts based on the silence of the cited reference and cannot be supported, particularly when the inference is in clear contradiction with the plain teachings of the reference itself. For instance, Appellants stress that the plain meaning of the terms "modify" and "change" would imply that *an* existing protocol is changed or modified, and not that multiple versions (*e.g.*, older and most current) of a protocol would remain residing on a server after such a modification. There simply is no support for the Examiner's assertion the previous version of the protocol would continue to exist. To the contrary, Brown clearly states that a drawback of the prior art is that "researchers are unable to modify a clinical protocol while in progress" and that if such a solution is provided, "morbidity and mortality associated with evaluation of new drugs could be *substantially* reduced." Brown, col. 2, ll. 58-67. Thus, based on the clear teachings of Brown, a researcher would *always* want to use the *most recent* version of a protocol in order to acquire the most reliable data while reducing possible harm to the test subjects. In other words, old and out-of-date protocols would *never* be used again due to morbidity and mortality concerns discussed above and, therefore, there would be no need to store

old versions of testing protocols, as these old versions would never become candidates for selection during the remainder of the drug testing trial.

In the Answer, the Examiner acknowledged that once modified, an old protocol would never be used. *See* Examiner's Answer, p. 46. Nevertheless, the Examiner asserted, without support, that old versions of the protocol would remain in a database even if they are never again to be candidates for implementation. *See id.* In view of the teachings of Brown summarized above, however, Appellants respectfully submit that the Examiner's interpretation is baseless and that the Examiner has not met the burden of showing that Brown discloses a template much less a template is selected from a *plurality of templates* stored in a centralized database.

Response to Rejections under Section 112, second paragraph

With respect to the rejection of claim 1 under Section 112, second paragraph, Appellants submit that one skilled in the art will readily understand the meaning of the term "tracking," when used in the context of databases. As stated in the Appeal Brief, tracking generally refers to monitoring or cross referencing changes in data to ensure that a user is provided with the most current data on request, or in some cases, to provide information as to how a data point of interest has progressed over time. *See* Appeal Brief, pp. 13-14. In the Answer, the Examiner continued to refer to the definition of "track" as defined in *Microsoft's Computer Dictionary*, which states "in data management, to follow the flow of information through a manual or automated system" (hereinafter the "Microsoft definition"). *See* Examiner's Answer, p. 30. Based on this definition, the Examiner interpreted the term "tracking" as being equivalent to "updating." *Id.* Appellants respectfully disagree.

To the contrary, the act of following the flow of information through a system by itself would not constitute the act of "updating," as would be understood by one skilled in the art. Rather, the plain meaning of updating would generally encompass overwriting old values with new values. Indeed, this is meaning is consistent with the interpretation proffered by the Examiner in advancement of the argument that an "updated protocol" and an older version of the protocol constitute a *plurality* of templates, as discussed above. Instead, the Microsoft definition

actually appears to be consistent with Appellants' use of the term tracking, as discussed above (e.g., following the flow/progress of information). Further, Appellants reiterate that the recitation of "tracking" and "updating" as two separate steps in claim 1 would preclude an interpretation that these terms are analogous.

Response to Rejections under Section 103

With regard to the rejections under Section 103, the Examiner cited either Brown alone, or Brown in combination with Goldwasser, U.S. Patent No. 4,737,921 (hereinafter Goldwasser), Rice et al., U.S. Pre-Grant Publication No. 2002/0042723 A1 (hereinafter "Rice"). Appellants respectfully submit that these additionally cited references, either alone or in combination, fail to obviate the deficiencies of Brown. Thus, no *prima facie* case of obviousness is believed to exist.

Conclusion

In conclusion, Appellants reiterate that the Examiner has failed to establish a *prima facie* case of anticipation or obviousness with regard to the pending claims based on the cited references and has also failed to set forth a convincing line of reasoning to support the Section 112, second paragraph, rejection of claim 1. Therefore, for at least the reasons set forth above, as well as the arguments set forth in the previously filed Appeal Brief, Appellants respectfully submit to the Board that independent claims 1, 14, 17, 30, and 33, as well as each of their respective dependent claims, are allowable over Brown, Goldwasser, or Rice, taken alone or in combination. As such, Appellants respectfully request that the Board direct the Examiner to reverse all the rejections of the pending claims.

Respectfully submitted,

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